MAR 27 2000

K000315

GE Medical Systems

PO Box 414, W-709
Milwaukee, WI 53201
USA

SUMMARY OF SAFETY AND EFFECTIVENESS

- This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- Identification of Submitter
  Larry A. Kroger, Ph.D., 414-544-3894, January 31, 2000

- Identification of the Product
  Ventricular Analysis Toolkit Option

  Manufactured by: GE Medical Systems
  3200 N. Grandview Blvd.
  Waukesha, WI 53188

- Device Description

  The Ventricular Analysis Toolkit Option is a software package that can be used in conjunction with multi-phase, multi-slice GE Signa Cardiac MR images to semi-automatically calculate and display various left ventricular (LV) and right ventricular (RV) functional parameters.

- Indications for Use

  The GE Ventricular Analysis Toolkit (VAT) is a software package that can be used in conjunction with multi-phase, multi-slice GE Signa MR Cardiac Images to semi-automatically calculate and display various Left Ventricular and Right Ventricular functional parameters such as End Systolic and End Diastolic Volumes, Stroke Volume, LV Ejection Fraction including Peak Filling and Ejection Rates, Myocardial Mass Calculations, and Regional Wall Motion Display and Analysis. When interpreted by a trained physician, these parameters may be useful in the determination of a diagnosis.

- Comparison with Predicate

  The Ventricular Analysis Toolkit is substantially equivalent to a subset of basic, manual image analysis tools included with the GE Signa MR System (K980114). All of the analysis routines provided in the VAT package can be accomplished manually using two basic tools (region of interest and

PO Box 414, W-709
Milwaukee, WI 53201
USA

SUMMARY OF SAFETY AND EFFECTIVENESS

measure distance) and simple arithmetic. However, the time required to complete the requisite manual operations on a full set of cardiac image data (typically more that 150 images) is considered prohibitive. The VAT package automates the series of manual steps required to perform the various analyses making these analyses more practical from a user productivity standpoint.

° Summary of Studies

The Ventricular Analysis Toolkit Option was evaluated to the IEC 601-2-33 International medical equipment safety standard for Magnetic Resonance Systems. Evaluation testing was done to verify the performance of the option which included the software feature tests which focused on verifying that the information displayed and after computation are identical with the calculations.

° Conclusions

It is the opinion of GE that the Ventricular Analysis Toolkit Option does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2000

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
Medical Systems, Inc.
P.O. Box 414, W-709
Milwaukee, WI 53201

Re: K000315
GE Ventricular Analysis Toolkit Option
Dated: January 31, 2000
Received: February 1, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known):_____

Device Name: GE Ventricular Analysis Toolkit (VAT)

Indications For Use:

The GE Ventricular Analysis Toolkit (VAT) is a software package that can be used in conjunction with multi-phase, multi-slice GE Signa MR Cardiac Images to semi-automatically calculate and display various Left Ventricular and Right Ventricular functional parameters such as End Systolic and End Diastolic Volumes, Stroke Volume, LV Ejection Fraction including Peak Filling and Ejection Rates, Myocardial Mass Calculations, and Regional Wall Motion Display and Analysis. When interpreted by a trained physician, these parameters may be useful in the determination of a diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feygin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000315

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)